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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner

Unassigned

Group Art Unit:

1642

:

Applicant

Jurg Tschopp

Serial No.

09/520,489

Filing Date

March 8, 2000

For

APRIL- A NOVEL PROTEIN WITH GROWTH

EFFECTS

New York, New York July 19, 2000

Hon. Assistant Commissioner for Patents Washington, D.C. 20231

TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT

Sir:

Transmitted herewith is an Information Disclosure Statement in the above-identified application. This Statement is submitted:

- [] within three months of the application filing date;
- [X] more than three months from the application filing date but before the mailing date of the first Office Action on the merits.

In accordance with 37 C.F.R. § 1.97, submission of this Statement requires no fee. However, if for any reason a fee is due, the Commissioner is hereby authorized to



charge payment of any fees required in connection with this JUL 252000 Information Disclosure Statement to Deposit Account No. 06-1075. A duplicate copy of this letter is transmitted herewith.

Respectfully submitted,

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Sir:

Pursuant to 37 C.F.R. §§ 1.56 and 1.97, applicant hereby makes the following references of record in the above-identified patent application:

U.S. PATENT DOCUMENTS

5,176,996	1/5/93	Hogan et al.
5,264,564	11/23/93	Matteucci
5,256,775	10/26/93	Froehler
4,816,567	3/28/89	Cabilly et al.

FOREIGN PATENT DOCUMENTS

WO	99/50416	10/7/99	PCT	C12N	15/19
WO	97/33902	9/18/97	PCT	С07Н	21/02

OTHER DOCUMENTS

Smith et al., 1993, CD30 Antigen, A Marker For Hodgkin's Lymphoma, Is A Receptor Whose Ligand Defines An Emerging Family Of Cytokines With Homology To TNF, Cell, 73:1349-1360

Smith, 1994, Virus Strategies For Evasion Of The Host Response To Infection, Trends In Microbiology, 2:81-88

Smith et al., 1990, A Receptor For Tumor Necrosis Factor Defines An Unusual Family Of Cellular And Viral Proteins, Science, 248:1019-1023

Kohno et al., 1990, A Second Tumor Necrosis Factor Receptor Gene Product Can Shed A Naturally Occurring Tumor Necrosis Factor Inhibitor, PNAS, 87:8331-8335

Loetscher et al., 1990, Molecular Cloning And Expression Of The Human 55kd Tumor Necrosis Factor Receptor, Cell, 61:351-359

Schall et al., 1990, Molecular Cloning And Expression Of A Receptor For Human Tumor Necrosis Factor, Cell, 61:361-370

Jones et al., 1989, Structure Of Tumor Necrosis Factor, Nature, 338:225-228

Eck et al., 1989, The Structure Of Tumor Necrosis Factor-Alpha at 2.6 Å Resolution, J. Biol. Chem., 264:17595-17605

Funakoshi et al., 1994, Inhibition Of Human B-Cell Lymphoma Growth By CD40 Stimulation, Blood, 83:2787-2794

Brojatsch et al., 1996, CAR1, a TNFR-Related Protein, Is A Cellular Receptor For Cytopathic Avian Leukosis-Sarcoma Viruses And Mediates Apoptosis, Cell, 87:845-855

Montgomery et al., 1996, Herpes Simplex Virus-1 Entry Into Cells Mediated By A Novel Member Of The TNF/NGF Receptor Family, Cell, 87:427-436

Nagata, 1997, Apoptosis By Death Factor, Cell, 88:355-365

Sytwu et al., 1996, The Roles of Fas/APO-1 (CD95) And TNF In Antigen-Induced Programmed Cell Death In T Cell Receptor Transgenic Mice, Immunity, 5:17-30

Zheng et al., 1995, Induction Of Apoptosis In Mature T Cells By Tumour Necrosis Factor, Nature, 377:348-351

Lee et al., 1996, T Cell Receptor-Dependent Cell Death Of T Cell Hybridomas Mediated By The CD30 Cytoplasmic Domain In Association With Tumor Necrosis Factor Receptor-Associated Factors, J. Exp. Med., 183:669-674

Amakawa et al., 1996, Impaired Negative Selection Of T Cells In Hodgkin's Disease Antigen CD30-Deficient Mice, Cell, 84:551-562

Vassalli, 1992, The Pathophysiology Of Tumor Necrosis Factors, Ann. Rev. Immunol., 10:411-452

van der Krol et al., 1988, Modulation Of Eukaryotic Gene Expression By Complementary RNA or DNA Sequences, Biotechniques, 6:958-976

Tracey, K., 1992, in <u>Tumor Necrosis Factors</u>. <u>The Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 255-273

Waage, A., 1992, in <u>Tumor Necrosis Factors</u>. The <u>Molecules</u> <u>And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 275-283

Roodman, G.D., 1992, in <u>Tumor Necrosis Factors. The Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 117-129

Nakane, A., 1992, in <u>Tumor Necrosis Factors</u>. <u>The Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 285-292

- Clark, I.A. et al., 1992, in <u>Tumor Necrosis Factors</u>. The <u>Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 303-328
- Grau, G.E. et al., 1992, in <u>Tumor Necrosis Factors. The Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 329-340
- Piguet, P.F., 1992, in <u>Tumor Necrosis Factors</u>. <u>The Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 341-354
- Wong, G.H.W. et al., 1992, in <u>Tumor Necrosis Factors</u>. The <u>Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 371-381
- Malik, S.T.A., 1992, in <u>Tumor Necrosis Factors. The Molecules And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 407-423
- Fox, D.A., 1995, Biological Therapies: A Novel Approach To The Treatment Of Autoimmune Disease, Am. J. Med., 99:82-88
- Goeddel, D. et al., 1986, Tumor Necrosis Factors: Gene Structure And Biological Activities, Cold Spring Harbor Symposium Quant. Biol., 51:597-609
- Trinchieri, G., in <u>Tumor Necrosis Factors</u>. <u>The Molecules</u> <u>And Their Emerging Role In Medicine</u>, B. Beutler (ed), Raven Press, NY, p. 515-530
- Tartaglia, L.A. et al., 1991, The Two Different Receptors For Tumor Necrosis Factor Mediate Distinct Cellular Responses, Proc. Natl. Acad. Sci. USA, 88:9292-9296
- Tartaglia, L.A. and Goeddel, D.V., 1992, Two TNF Receptors, Immunol. Today, 13:151-153
- Kriegler, M. et al., 1988, A Novel Form Of TNF/Cachectin Is A Cell Surface Cytotoxic Transmembrane Protein: Ramifications For The Complex Physiology of TNF, Cell, 53:45-53
- Luettig, B. et al., 1989, Evidence For The Existence Of Two Forms Of Membrane Tumor Necrosis Factor: An Integral Protein And A Molecule Attached To Its Receptor, J. Immunol., 143:4034-4038
- Ware, C.F. et al., 1995, in <u>Pathways For Cytolysis</u>, G.M. Griffiths and J. Tschopp (Eds.), Springer-Verlag, Berlin, Heidelberg, p. 175-218

Paul, N.L. and Ruddle N.H., 1988, Lymphotoxin, Ann. Rev. Immunol., 6:407-438

Crowe, P.D. et al., 1994, A Lymphotoxin-Beta-Specific Receptor, Science, 264:707-710

Browning, J.L. et al., 1993, Lymphotoxin Beta, A Novel Member Of The TNF Family That Forms A Heteromeric Complex With Lymphotoxin On The Cell Surface, Cell, 72:847-856

Browning, J.L. et al., 1995, Characterization Of Surface Lymphotoxin Forms, J. Immunol., 154:33-46

De Togni, P. et al., 1994, Abnormal Development Of Peripheral Lymphoid Organs In Mice Deficient In Lymphotoxin, Science, 264:703-707

Shanafelt M-C, et al., 1995, J. Immunol., 154:1683-1690

Browning, J. and Ribolini, A., 1989, Studies On The Differing Effects Of Tumor Necrosis Factor And Lymphotoxin On The Growth Of Several Human Tumor Lines, J. Immunol., 143:1859-1867

Browning, J. et al., 1996, Signaling Through The Lymphotoxin Beta Receptor Induces The Death Of Some Adenocarcinoma Tumor Lines, J. Exp. Med., 183:867-878

Suda, T. et al., 1995, Expression Of The Fas Ligand In Cells Of T Cell Lineage, J. Immunol., 154:3806-3813

Trauth, B.C. et al., 1989, Monoclonal Antibody-Mediated Tumor Regression By Induction Of Apoptosis, Science, 245:301-305

Yonehara, S. et al., 1989, A Cell-Killing Monoclonal Antibody (Anti-Fas) To A Cell Surface Antigen Co-Downregulated With The Receptor Of Tumor Necrosis Factor, J. Exp. Med, 169:1747-1756

Nagata, S. and Golstein, P., 1995, The Fas Death Factor, Science, 267:1449-1456

Falk, M.H. et al., 1992, Expression Of The APO-1 Antigen In Burkitt Lymphoma Cell Lines Correlates With A Shift Towards A Lymphoblastoid Phenotype, Blood, 79:3300-3306

Rieux-Laucat, F. et al., 1995, Mutations In Fas Associated With Human Lymphoproliferative Syndrome And Autoimmunity, Science, 268:1347-1349

Takahashi, T. et al., 1994, Generalized Lymphoproliferative Disease In Mice, Caused By A Point Mutation In The Fas Ligand, Cell, 76:969-976

Watanabe-Funkunaga, R. et al., 1992, Lymphoproliferation Disorder in Mice Explained by Defects in Fas Antigen That Mediates Apoptosis, Nature, 356:314-317

Galle, P.R. et al., 1995, Involvement Of The CD95 (APO-1/Fas) Receptor And Ligand In Liver Damage, J. Exp. Med., 182:1223-1230

Silvestris, F. et al., 1995, Autoreactivity In HIV-1 Infection: The Role Of Molecular Mimicry, Clin. Immunol. Immunopathol., 75:197-205

Katsikis, P.D. et al., 1995, Fas Antigen Stimulation Induces Marked Apoptosis of T Lymphocytes In Human Immunodeficiency Virus-Infected Individuals, J. Exp. Med., 181:2029-2036

Badley, A.D. et al., 1996, Upregulation Of Fas Ligand Expression By Human Immunodeficiency Virus In Human Macrophages Mediates Apoptosis Of Uninfected T Lymphocytes, J. Virol., 70:199-206

Wiley, S.R. et al., 1995, Identification And Characterization Of A New Member Of The TNF Family That Induces Apoptosis, Immunity, 3:673-682

Gauchat, J.F. et al., 1993, Human CD40-Ligand: Molecular Cloning, Cellular Distribution And Regulation Of Expression By Factors Controlling IgE Production, FEBS Lett., 315:259-266

Funakoshi, S. et al., 1994, Inhibition Of Human B-Cell Lymphoma Growth By CD40 Stimulation, Blood, 83:2787-2794

Allen, R.C. et al., 1993, CD40 Ligand Gene Defects Responsible For X-Linked Hyper-IgM Syndrome, Science, 259:990-993

Biancone, L. et al., 1995, Inhibition Of The CD40-CD40 Ligand Pathway Prevents Murine Membranous Glomerulonephritis, Kidney Int., 48:458-468

Mohan, C. et al., 1995, Interaction Between CD40 And Its Ligand gp39 In The Development Of Murine Lupus Nephritis, J. Immunol., 154:1470-1480

Ruby, J. et al., 1995, CD40 Ligand Has Potent Antiviral Activity, Nature Medicine, 1:437-441

Wang, Z. et al., 1995, Induction Of bcl-x by CD40 Engagement Rescues sIg-Induced Apoptosis In Murine B Cells, J. Immunol., 155:3722-3725

Cleary, A.M., et al., 1995, J. Immunol., 155:3329

Hess, S. and Engelmann, H., 1996, A Novel Function Of CD40: Induction Of Cell Death In Transformed Cells, J. Exp. Med., 183:159-167

Goodwin, R.G., et al., 1993, Molecular And Biological Characterization Of A Ligand For CD27 Defines A New Family Of Cytokines With Homology To Tumor Necrosis Factor, Cell, 73:447-456

Goodwin R.G. et al., 1993, Molecular Cloning Of A Ligand For The Inducible T Cell Gene 4-1BB: a Member Of An Emerging Family Of Cytokines With Homology To Tumor Necrosis Factor, Eur. J. Immunol., 23:2631-2641

Stein C.A. et al., 1988, Oligodeoxynucleotides As Inhibitors Of Gene Expression: A Review, Cancer Res, 48:2659-2668

Winter G. and Milstein C., 1991, Man-Made Antibodies, Nature, 349:293-299

Arulanandam A.R.N. et al., 1993, A Soluble Multimeric Recombinant CD2 Protein Identifies CD48 As A Low Affinity Ligand For Human CD2: Divergence Of CD2 Ligands During The Evolution Of Humans And Mice, J. Exp. Med., 177:1439-1450

Queen et al., 1989, A Humanized Antibody That Binds To The Interleukin 2 Receptor, Proc Natl. Acad Sci., 86:10029-10033

Leung D.W., et al., 1989, A Method For Random Mutagenesis Of A Defined DNA Segment Using A Modified Polymerase Chain Reaction, Technique, 1:11-15

Narang, S.A., 1983, DNA Synthesis, Tetrahedron, 39:3-22

Itakura K. et al., 1981, Chemical Synthesis And Application Of Oligonucleotides Of Mixed Sequence, Recombinant DNA, Proc 3rd Cleveland Sympos. Macromolecules, ed. AG Walton, Amsterdam: Elsevier, pp. 273-289

Itakura K. et al., 1984, Synthesis And Use Of Synthetic Oligonucleotides, Annu. Rev. Biochem., 53:323-356

Itakura K. et al., 1984, Expression In Escherichia coli Of A Chemically Synthesized Gene For The Hormone Somatostatin, Science, 198:1056-1063

Ike Y. et al., 1983, Solid Phase Synthesis Of Polynucleotides. VIII. Synthesis Of Mixed Oligodeoxyribonucleotides By The Phosphotriester Solid Phase Method, Nucleic Acid Res., 11:477-488

Scott J.K. et al., 1990, Searching For Peptide Ligands With An Epitope Library, Science, 249:386-390

Roberts B.L. et al., 1992, Directed Evolution Of A Protein: Selection Of Potent Neutrophil Elastase Inhibitors Displayed On M13 Fusion Phage, Proc. Natl. Acad. Sci., 89:2429-2433

Devlin J.J. et al., 1990, Random Peptide Libraries: A Source Of Specific Protein Binding Molecules, Science, 249:404-406

Cwirla S.E. et al., 1990, Peptides On Phage: A Vast Library Of Peptides For Identifying Ligands, Proc. Natl. Acad. Sci., 87:6378-6382

Adelman J.P. et al., 1983, In Vitro Deletional Mutagenesis For Bacterial Production Of The 20,000-Dalton Form Of Human Pituitary Growth Hormone, DNA, 2:183-193

Cunningham B.C. and Wells J.A., 1989, High-Resolution Epitope Mapping Of hGH-Receptor Interactions By Alanine-Scanning Mutagenesis, Science, 244:1081-1085

Crea R. et al., 1978, Chemical Synthesis Of Genes For Human Insulin, Proc. Natl. Acad. Sci. 75:5765-5769

Wells J.A. et al., 1985, Cassette Mutagenesis: An Efficient Method For Generation Of Multiple Mutations At Defined Sites, Gene, 34:315-323

Abreu-Martin, M.T. et al., 1995, Divergent Induction Of Apoptosis And IL-8 Secretion In HT-29 Cells In Response To TNF And Ligation Of Fas Ligand, J. Immunol., 155:4147-4154

Agematsu et al., 1995, CD27/CD70 Interaction Directly Drives B Cell IgG and IgM Synthesis, Eur J. Immunol., 25:2825-2829

Bodmer J.L., et al., 1997, TRAMP, A Novel Apoptosis-Mediating Receptor With Sequence Homology To Tumor Necrosis Factor Receptor 1 And Fas(APO-1/CD95), Immunity, 6:79-88

Browning J.L., et al., 1991, Lymphotoxin And An Associated 33-kDa Glycoprotein Are Expressed On The Surface Of An Activated Human T Cell Hybridoma, J. Immunol., 147:1230-1237

Browning J.L. et al., 1996, Preparation And Characterization Of Soluble Recombinant Heterotrimeric Complexes of Human Lymphotoxins alpha and beta, J. Biol. Chem., 271:8618-8626

Castro et al., 1996, Fas Modulation Of Apoptosis During Negative Selection Of Thymocytes Immunity, 5:617-627

Chen C-Y.A. and Shyu A-B., 1995, AU-Rich Elements: Characterization And Importance In mRNA Degradation, Trends In Biol. Sci. 20:465-470

Chicheportiche Y. et al., 1995, Identification In Mouse Macrophages Of A New 4Kb mRNA Present In Hematopoietic Tissues, Which Shares A Short Nucleotide Sequence With Erythropoietin mRNA, Biochem. Biophys. Res. Comm., 209:1076-1081

Chinnaiyan A.M. et al., 1996, Signal Transduction by DR3, A Death Domain-Containing Receptor Related To TNFR-1 And CD95, Science, 274:990-992

DeTogni P.D. et al., 1994, Abnormal Development Of Peripheral Lymphoid Organs In Mice Deficient In Lymphotoxin, Science, 264:703-707

DeBenedette M.A. et al., 1995, Role Of 401BB Ligand In Costimulation Of T Lymphocyte Growth And Its Upregulation On M12 B Lymphomas By cAMP, J. Exp. Med. 181:985-992

Degli-Esposti M.A. et al., 1997, Activation Of The Lymphotoxin Beta Receptor By Cross-Linking Induces Chemokine Production And Growth Arrest In A375 Melanoma Cells, J. Immunol., 158:1756-1762

Foy T.M. et al., 1996, Immune Regulation By CD40 And Its Ligand GP39, Ann. Rev. Immunol., 14:591-617

Gruss H-J et al., 1994, Pleiotropic Effects of The CD30 Ligand on CD30-expressing Cell Lines, Blood, 83:2045-2056

Gruss H-J and Dower S.K., 1995, Tumor Necrosis Factor Ligand Superfamily: Involvement In The Pathology Of Malignant Lymphomas, Blood, 85:3378-3404

Kitson J. et al., 1996, A Death-Domain-Containing Receptor That Mediates Apoptosis, Nature, 384:372-375

Pitti R.M. et al., 1996, Induction Of Apoptosis By Apo-2 Ligand, A New Member Of The Tumor Necrosis Factor Cytokine Family, J. Biol. Chem., 271:12687-12690



SmithC.A. et al., 1994, The TNF Receptor Superfamily Of Cellular And Viral Proteins: Activation, Costimulation, And Death, Cell, 76:959-962

Stüber E. and Strober W., 1996, The T Cell-B Cell Interaction Via OX40-OX40L Is Necessary For The T Cell-Dependent Humoral Immune Response, J. Exp. Med., 183:979-989

A copy of the aforementioned references, which are listed on the accompanying Form PTO-1449 (submitted in duplicate), are enclosed herewith.

Applicant requests that these references be (1) fully considered by the Patent and Trademark Office during the examination of this application; and (2) printed on any patent which may issue on this application. Applicant also requests that a copy of Form PTO-1449, as considered and initialed by the Examiner, be returned with the next communication.

An early and favorable action is respectfully requested.

Respectfully submitted,

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